

REMARKS

A Petition for Extension of Time is being concurrently filed with this Amendment. Thus, this Amendment is being timely filed.

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

Claims 9, 12, 15, 18 and 21-30 are currently pending in the present application, wherein claims 9, 12, 15, 18 and 21 stand withdrawn from consideration.

In the present Amendment, claim 30 has been amended. No new matter has been added by way of the amendment to claim 30 as subject matter is actually being deleted.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 112, Second Paragraph

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph, for asserted lack of definiteness (see Office Action at page 2-3). Applicants respectfully traverse as the disputed claim language has been deleted from claim 30, which renders the rejection moot. Thus, reconsideration and withdrawal of this rejection are respectfully requested.

Issues under 35 U.S.C. § 103(a)

Claims 22-29 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Konzak et al. (U.S. Patent No. 6,362,393; hereinafter “Konzak et al.”) in view of Lyznik et al., *The Plant Cell*, Vol. 8(2), pp. 177-186 (1995) (hereinafter “Lyznik et al.”) (see Office Action at pages 3-8). Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested. Overall, Applicants respectfully submit that one of ordinary skill in the art would not have the proper rationale, suggestion or motivation to combine the references that are cited by the Examiner.

No Disclosure of All Claimed Features and Improper Combination of References

The cited references fail to describe object of the present invention and do not even recognize the problem which the present invention solves. In other words one of ordinary skill in the art upon reading the cited references would not recognize even the problem in the art. In this regard, the invention as a whole is not restricted to the specific subject matter claimed, but also embraces its properties and the problem(s) it solves. *In re Wright*, 6 USPQ2d 1959, 1962 (Fed. Cir. 1988).

Regarding the object of the present invention and the cited combination of Konzak et al. and Lyznik et al., the object of the invention by Konzak et al is described in the top of the Abstract thereof which reads: “The present invention provides methods for generating doubled haploid and/or haploid plants from microspores.” More particularly, while novel cultivars are usually obtained after crosses over a period of several years (see column 1, lines 19-26 of Konzak et al.), doubled haploid plants are generated by the method of Konzak et al. Thus, the

object of the present invention, that is, to promote the efficiency of gene transfer, is not at all described or suggested by the cited primary reference. Konzak et al. merely state that, as an embodiment of their method, the method optionally comprises “the step of genetically transforming the microspores” (see column 4, lines 31-33).

Further, in Konzak et al., the *Agrobacterium* method (see column 12, lines 53-54) is merely mentioned (at column 12, lines 53-54) as a method of genetic transformation in addition to the methods such as by “particle gun” and “electroporation” (see column 4, lines 36-41). In fact, Konzak et al. present no example showing the experimental data of a gene transfer. Thus, it is apparent that Konzak et al. were not aware of the object or potential advantages of the present invention.

Similarly, Lyznik et al. fails to recognize the same object. Lyznik et al. is cited as stated in the Office Action at page 4, lines 9-10 (e.g., centrifugation speed). The cited secondary reference of Lyznik et al. is a paper disclosing an invention related to heat-inducible expression as can be seen from its title. Thus, the object of the present invention, that is, to promote the efficiency of gene transfer, is not at all described or suggested in this reference as well.

Lyznik et al. even fails to disclose the term “*Agrobacterium*,” which is a part of the present invention. Applicants note that all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See M.P.E.P. § 2143.03.

Even more so, the centrifugation conducted by Lyznik et al. is one carried out after gene transfer (see the middle part of page 183, right column, under “Tissue culture and protoplast transformation”) in order to collect the GUS protein in the extract solution (supernatant) after

destructing the cells (see the lower part of page 183, right column, under “GUS activity, NPT-II activity, and protein assays”).

Thus, in the cited references, even when combined, fail to describe the object of the present invention as well as the problems which the present invention tries to solve. Further, no use suggesting the present invention is described in these references nor recognized by the state of the art, and the effects of the present invention are not described in any of the cited references.

In both of the cited references, centrifugation is performed in order to isolate the protoplasts or microspores. This is apparent from the very descriptions cited by the Examiner. More particularly, Applicants note column 4, lines 6-9 of Konzak et al., which reads: “The treated microspores are isolated by . . . subjecting the filtrate to density centrifugation”. Konzak et al. at column 4, line 14 reads: “The isolated, treated microspores are then cultured . . . “. Thus, it is apparent that the centrifugation employed in Konzak et al. is an operation for isolation. That is, Konzak et al. merely refer to the centrifugation as a step for isolation in the method of generating doubled haploid plants.

Applicants also note page 18, right column, last paragraph in Lyznik et al., which reads: “. . . pelletized by centrifugation . . .”. Thus, it is apparent that the centrifugation is carried out for pelletizing the sample. Also in Lyznik et al., the centrifugation is conducted after gene transfer (see middle part of page 183, right column, “Tissue culture and protoplast transformation”), in order to collect the GUS protein in the extract solution (supernatant) after destructing the cells (lower part of page 183, right column, “GUS activity, NPT-II activity, and protein assays”). This is in sharp contrast to the instantly claimed feature of “contacting step is carried out after or simultaneously to said centrifugation”, wherein this feature is recited in independent claim 22 of

the present application. And as M.P.E.P. § 2143.03 directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness, which would include the mentioned contacting step that is carried out after or simultaneously to said centrifugation. Thus, Lyznik et al. fails to disclose or suggest the use or effects that would lead to the present invention.

Even if there is some rationale for those skilled in the art to employ centrifugation as an effective process for isolating a plant tissue as the Examiner points out, which Applicants respectfully dispute, Applicants note the feature of “wherein said centrifugation promotes efficiency of the transformation of the desired gene into said tissue or plant” of pending claim 22. There is no such description of this in the cited references. Thus, it is apparent to one of ordinary skill in the art that the effect of the present invention is not at all described or suggested in the cited references and is totally unexpected from the cited combination of references.

In order to properly combine references, the possibility of some improvement attained by the combination of the references must be described or suggested in at least one of the references. Applicants note that M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for

determining obviousness, wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (U.S. 2007).

But regarding the proper rationale, under *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993) and *Ex parte Gerlach*, 212 USPQ 471 (BPAI 1980), the Examiner cannot equate that which is within the capabilities of one skilled in the art (“one of ordinary skill in the art could adjust the parameters”) with obviousness. In other words, there is nothing in the statutes or the case law which makes that which is within the capabilities of one skilled in the art synonymous with obviousness. Applicants respectfully submit that the cited references are combined merely based on such capabilities of the skilled artisan. There cannot be such any proper reason or suggestion of improvement in the cited references when the authors thereof are not even aware of the problem which the present invention tries to solve and that are totally silent about the use and effects of the present invention.

Unexpected Results

Applicants note that one of the *Graham* factors is the evaluation of any evidence of secondary considerations (e.g., commercial success; unexpected results).

At page 5 of the Office Action, the Examiner points out: “The evidence of nonobviousness does not provide support for the instant claims broad range of centrifugation of 1000G to 150,000G for 1 second to 4 hours. Objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support”.

In response to this, Applicants herein summarize the significances of the previously filed Declarations and also submit two new Rule 132 Declarations so as to concretely explain the unexpected effects of the present invention. The explanation below will show that the scopes of the claims are proper.

(i) Previous Rule 132 Declaration

The Rule 132 Declaration filed on November 13, 2007 shows that centrifugation treatment at an acceleration of not less than 1000G before the gene transfer prominently increases the efficiency of gene transfer. The present invention is directed to “a method for promoting the efficiency of gene transfer”. The Examiner refers to the fact that “Table 1 shows some GUS activity with 760 x g”. However, the Declaration of 2007 clearly shows that there is a prominent difference between the “some GUS activity” with 760G and the GUS activities at 1000G or more, that is, the results clearly show the effects of the present invention. Thus, the Declaration of 2007 clearly shows that “centrifugation treatment before the gene transfer prominently increases the efficiency of gene transfer”. It is believed that this evidence of record is not being properly considered.

As for the data of high accelerations, such experimental data is shown in the Examples in the specification of the present application. In the Examples in the present specification, it is demonstrated that the effects of the present invention can be obtained when the centrifugation is carried out at high accelerations.

(ii) Rule 132 Declarations Submitted Herewith

Further, Applicants respectfully refer the Examiner to the new Rule 132 Declarations attached hereto. The new Rule 132 Declarations more clearly show that the effects of the present invention is commensurate with the scope of the claims now on file (see page 5 of the Office Action).

The first new Rule 132 Declaration contains experimental data showing the effect of the centrifugation for 1 second or more; the second new Rule 132 Declaration contains experimental data showing the effect of the centrifugation for 4 hours.

More specifically, the first new Rule 132 Declaration shows that GUS expression is increased to twice to three times by a centrifugation of 1 second or more (1 second, 10 seconds or 60 seconds) when compared with the case where no centrifugation is carried out. A centrifugation at 20,000G for 1 second increased the GUS activity to 7 to 13 times. Thus, even if the centrifugation is for only one second at a claimed acceleration, the gene transfer efficiency is largely increased. This is evidence of the unexpected advantages of the present invention, and is commensurate with the scope of the instant claims.

The second new Rule 132 Declaration shows that a centrifugation for 4 hours increased the gene transfer efficiency to the same degree by the centrifugation for 10 hours (Fig. 2, Table 1). This is also evidence of the unexpected results of the present invention and is commensurate with the scope of the instant claims.

With the mentioned experiments in the Rule 132 Declarations of record to date, Applicants respectfully submit that this evidence is commensurate in scope with the pending claims. Therefore, even if the Examiner has hypothetically established a *prima facie* case of

obviousness, a point not conceded by Applicants, the unexpectedly superior results according to the present invention rebut such a hypothetical *prima facie* case of obviousness.

Therefore, it is believed that the present invention is not obvious over the cited combination of references, and the 103(a) rejection has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

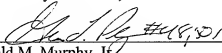
Art Unit 1661

Reply to Office Action of January 8, 2009

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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Attachments: Declaration under 37 C.F.R. § 1.132 (7 pages)
Declaration under 37 C.F.R. § 1.132 (5 pages)